manufacturers of this proposed regulation is expected to be negligible. Manufacturers could, of course, revise their labeling before the effective date of the regulation, and the agency encourages them to do so.

b. *Costs to the drug industry.* There are 815 currently marketed prescription and OTC drug products that are administered to mucous membranes (through oral, nasal, rectal or vaginal routes) and that contain FD&C Yellow No. 6. The cost of printing a drug label is estimated to be $258 per label. Therefore, the printing cost associated with this proposed regulation is estimated to be $210,270. FDA assumes that almost all existing label stocks for drug products will be depleted by the proposed effective date. Therefore, this proposed regulation will result in little or no inventory disposal costs. Administrative costs are estimated to be approximately $850 per firm. FDA estimates that approximately 113 firms will be affected by this regulation. Therefore, the administrative costs are estimated to be $96,050. The total one-time cost to the drug industry of declaring FD&C Yellow No. 6 on the label is $306,320.

2. Benefits

The benefit of requiring the labeling of FD&C Yellow No. 6 on butter, cheese, ice cream, and drug products administered to mucous membranes is ultimately the reduction of allergic-type reactions. FDA does not have information to quantify the benefits of this proposed regulation.

C. Summary

FDA has determined that this proposed rule is not a significant rule as defined by Executive Order 12866. The requirement to include FD&C Yellow No. 6 on the labels of butter, cheese, ice cream, and drug products administered to mucous membranes would result in a one-time cost of about $306,000.

IX. Comments

Interested persons may, on or before October 4, 1995, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 74

Color additives, Cosmetics, Drugs.

21 CFR Part 133

Cheese, Food grades and standards, Food labeling.

21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that the suspension of the effective date of 21 CFR 201.20(c) at 53 FR 49138, December 6, 1988, be removed and 21 CFR parts 74 and 133 be amended as follows:

PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

1. The authority citation for 21 CFR part 74 continues to read as follows:

Authority: Secs. 201, 401, 402, 403, 409, 501, 502, 505, 601, 602, 701, 721 of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e).

2. Section 74.705 is amended by revising paragraph (d)(2) to read as follows:

§ 74.705 FD&C Yellow No. 5.

* * * * *

(d) * * *

(2) Butter, cheese, and ice cream that contain FD&C Yellow No. 5 shall be labeled in accordance with § 101.22(k)(1) of this chapter.

* * * * *

3. Section 74.706 is amended by adding paragraph (d)(2) to read as follows:

§ 74.706 FD&C Yellow No. 6.

* * * * *

(d) * * *

(2) Butter, cheese, and ice cream that contain FD&C Yellow No. 6 shall be labeled in accordance with § 101.22(k)(1) of this chapter.

* * * * *

4. Section 74.1706 is amended by adding paragraph (c)(2) to read as follows:

§ 74.1706 FD&C Yellow No. 6.

* * * * *

(c) * * *

(2) The label of over-the-counter (OTC) and prescription drug products intended for human use and administered orally, nasally, rectally, or vaginally containing FD&C Yellow No. 6 shall specifically declare the presence of FD&C Yellow No. 6 by listing the color additive using the name FD&C Yellow No. 6. The labels of certain drug products subject to this labeling requirement that are also cosmetics, such as antibacterial mouthwashes and fluoride toothpastes, need not comply with this requirement provided they comply with the requirements of § 701.3 of this chapter.

* * * * *

PART 133—CHEESES AND RELATED CHEESE PRODUCTS

5. The authority citation for 21 CFR part 133 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 721 of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 379e).

§ 133.123 [Amended]

6. Section 133.123 *Cold-pack and club cheese* is amended by removing paragraphs (f)(1) and (f)(2).

Dated: July 6, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–17831 Filed 7–20–95; 8:45 am]

BILLING CODE 4160–01–P

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21 CFR Part 101

[Docket No. 93P–0448]

Food Labeling; Serving Sizes; Reference Amount for ''Salt, Salt Substitutes, Seasoning Salts (e.g., Garlic Salt)''

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the nutrition labeling regulations to change the reference amount customarily consumed per eating occasion for the food category ''salt, salt substitutes, seasoning salts (e.g., garlic salt)'' from a weight-based reference amount of 1 gram (g) to a volume-based reference amount of 1/4 teaspoon (tsp). This action is necessary to provide consistency with the agency's criteria for determining volumetric versus weight-based reference amounts for all product categories.

DATES: Written comments by October 4, 1995.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Ellen M. Anderson, Center for Food

Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5662.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 19, 1990 (55 FR 29517 at 29532), as part of its effort to make the food label more useful and understandable to consumers, FDA proposed standard serving sizes for 159 food product categories based on the amount of food commonly consumed per eating occasion by persons 4 years of age or older. For the category ''salt, seasoning salt (e.g., garlic salt),'' the agency proposed a serving size of 1 g.

On November 8, 1990, however, before FDA could issue a final rule in the serving size rulemaking, Congress passed the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). This statute amended the Federal Food, Drug, and Cosmetic Act (the act) to require that virtually all foods bear nutrition information that is based on a serving size that reflects the amount of food that is customarily consumed and that is expressed in a common household measure that is appropriate to the food (section 403(q)(1)(A)(i) of the act (21 U.S.C. 343(q)(1)(A)(i))). The new law also directed FDA to adopt regulations that establish standards to define serving sizes (section 2(b)(1)(B) of the 1990 amendments (21 U.S.C. 343 note)).

In response to the new law, FDA, among other actions, issued a reproposal on serving sizes (56 FR 60394, November 27, 1991). In that reproposal, FDA carried forward the 1-g value for salt, although it called this amount the ''reference amount customarily consumed'' to reflect the requirements of the new law. FDA chose this amount based in part on its tentative determination to use weight-based amounts except in those instances in which it was demonstrably inappropriate to do so. The agency also included salt substitutes in the food category for salt and seasoning salts.

FDA received three comments on the proposed reference amount for salt (58 FR 2229 at 2260, January 6, 1993). One comment agreed with the proposed 1-g reference amount. The second comment also agreed with this amount, but it requested a voluntary declaration based on 1/4 tsp. The third comment argued that a weight-based reference amount was inappropriate for salt and requested that a volume-based reference amount be established. However, this comment did not include any data to support its assertions. Thus, in its final rule on serving sizes, FDA concluded that, in the absence of evidence to support a different reference amount, 1 g was the appropriate reference amount for ''salt, salt substitutes, seasoning salts (e.g., garlic salt)'' (58 FR 2229 at 2297).

II. The Petition

On November 19, 1993, FDA received a petition from Akzo Salt, Inc., that requested that FDA change the reference amount for salt from 1 g to a density-adjusted reference amount to be listed as ''x g-1/4 tsp.'' In support of its petition, the petitioner submitted the results of a consumer study of consumption patterns for salt and low-density salt and analytical data comparing the physical properties (including density) of salt and low-density salt. The company stated that the low-density salt product contains 33 percent less sodium by volume than regular table salt, that the consumer data demonstrate that equivalent volumes of low-density salt and regular salt are consumed, and that, therefore, consumers who use similar volumes of low-density and regular salt would consume 33 percent less sodium by using the low-density salt product rather than regular table salt. The company concluded that it should be permitted to communicate the benefits of its low-density salt product to consumers in a truthful manner, including making claims that would be prohibited under regulations established in response to the 1990 amendments.

On May 24, 1994, the petitioner amended its petition by submitting supplemental materials consisting of detailed information regarding the protocol, data tabulation, and results of the consumer study. The supplemental materials also included an independent evaluation of the results and conclusions of the consumer study.

On February 2, 1994, FDA received a comment that requested that the agency reject the petition and take no further action with regard to salt and salt products. The comment stated that amending the reference amount as requested by the petitioner would permit a comparative claim that would be contrary to the letter and intent of the 1990 amendments, which the comment claimed was to provide for comparison of two distinct foods and not two versions of the same food. The comment also argued that the proposed change would undermine the overall structure of FDA's regulation of nutrient content claims by acting as an incentive for manufacturers to extend their products with air or other nonnutritive substances in order to make claims. Finally, the comment asserted that the consumer study data submitted in the petition were incorrect and insufficient. On April 14, 1994, FDA received a response by the petitioner to the various arguments made in this comment.

FDA has carefully considered the information in this petition, the supplemental submission, and the comments. Based on its review, FDA finds that the petitioner has made a prima-facie case that a volume-based reference amount of 1/4 tsp for salt is more appropriate than the reference amount that FDA adopted in 1993 (Ref. 1). Therefore, in accordance with 21 CFR 10.30(e)(2)(i), FDA is granting the petition and proposing to change the reference amount for ''salt, salt substitutes, seasoning salts (e.g., garlic salt)'' from 1 g to 1/4 tsp. A discussion of the basis for the agency's action on the petition and for the proposed change in the reference amount follows.

III. Basis for the Proposed Action

A. The Appropriateness of a Weight-Based Reference Amount

As stated above, in the final rule on serving sizes, FDA adopted a weight-based reference amount of 1 g for ''salt, salt substitutes, seasoning salts (e.g., garlic salt)'' based on the agency's determination to use weight-based reference amounts unless such amounts were shown to be demonstrably inappropriate (58 FR 2229 at 2238) and on the lack of data showing that a weight-based reference amount was inappropriate for salt.

In the final rule on serving sizes, however, FDA outlined the circumstances in which a weight-based reference amount would not adequately reflect the amount of food customarily consumed per eating occasion (see comment 20 in 58 FR 2229 at 2238). The agency stated that weight-based reference amounts are inappropriate when foods within a product category vary considerably in density, that is, there is a density difference of 25 percent or more among the products in the category (see § 101.12(e) (21 CFR 101.12(e))), and the customarily consumed amounts for different products are more uniform when expressed in volume than in weight. As an example, the agency explained that, although the reference amount for the category ''Mixed Dishes: Measurable with cup, * * *'' is 1 cup, the g weights of different types of products within the category differ widely from about 160 g for seafood with vegetables without sauce to about 250 g for seafood stew. The use of a weight-based reference amount for this product category would result in serving sizes too large for some

products and too small for others. However, FDA found, based on consumption and usage data, that the volume amounts customarily consumed are similar for all products within this category. Thus, the agency concluded that a volume-based reference amount, rather than a weight-based reference amount, was appropriate for this class of foods.

Similarly, FDA changed the reference amount for peanut butter from ''30 g'' in the proposal to a volume-based amount of ''2 tbsp'' in the final rule in response to data demonstrating that there is a density variation of greater than 25 percent among peanut butters (whipped peanut butter is approximately 33 percent less dense than regular peanut butter), and that common cookbook usage of peanut butter is expressed by volume (e.g., tablespoon and cup) demonstrating that the amount customarily consumed in recipes that include peanut butter is measured by volume and not by weight (see comment 108 in the final rule for serving sizes, 58 FR 2229 at 2263). FDA concluded that the volume-based amount more accurately reflected the amount customarily consumed of the various types of peanut butter.

The agency does not agree with the comment that it received on the petition that a comparative claim between two versions of the same food (i.e., salt and low-density salt) would be contrary to the letter and intent of the 1990 amendments and would undermine FDA's regulation of nutrient content claims by encouraging the use of nonnutritive substances in order to make claims. In addition to providing for claims that compare similar kinds of foods (e.g., potato chips can serve as a reference food for potato chips) (see 21 CFR 101.13(j)), FDA provided procedures in § 101.12(e) to define reference amounts for aerated products to permit comparison of equal volumes of the aerated and nonaerated versions.

One purpose of the 1990 amendments was to help consumers maintain healthy dietary practices (see e.g., sections 403(q)(1) and (r)(2)(A)(ii)(II) of the act). In comment 138, in the final rule for serving sizes (58 FR 2229 at 2271), FDA specifically stated:

> In light of the current dietary guidelines for reducing fat and calorie intakes * * *, FDA acknowledges that it is desirable to have a wide selection of low fat and low calorie foods available to consumers. Some consumers may benefit from having such aerated foods if they consume an equivalent volume of aerated food as they would have the regular food, e.g., two instead of three aerated waffles.

Similarly, given the dietary guidelines recommending that people use salt and sodium in moderation (Refs. 3 through 5), if consumers consume equivalent volumes of low-density salt and regular salt, then it would be beneficial for consumers to have a variety of products available that are permitted to compare the sodium content of different types of salt and salt substitute products.

FDA has reviewed the materials in the petition and in the supplemental submission and comments. Based on this review, the agency concludes that the petitioner has made a prima-facie showing that a weight-based reference amount is not appropriate for salt. First, the density difference between low-density salt and conventional table salt is reported in the petition to be 33 percent, which supports that the densities of the foods in the salt products category vary considerably. Second, the consumer research data included in the supplemental submission provide evidence that similar volumes, rather than similar weights, of low- and high-density salt products are customarily consumed. For these reasons, FDA has tentatively determined that a weight-based reference amount is not appropriate for salt products. Therefore, FDA is proposing to make a change in the reference amount for salt.

B. Relief Requested of a Density-Adjusted Reference Amount

The petition requested a density-adjusted reference amount for the product category ''salt, salt substitutes, seasoning salts (e.g., garlic salt).'' However, there are several difficulties with using a density-adjusted reference amount for this product category.

FDA discussed density-adjusted reference amounts in the context of aerated products, specifically waffles, in comment 138 in the final rule on serving sizes (58 FR 2229 at 2271). In response to requests for a volumetric reference amount for waffles, the agency noted that the wide variability in size and shape of discrete products like waffles makes it difficult to establish a volume for the aerated version that would be equivalent to the reference amount of the regular counterpart. Consequently, FDA permitted manufacturers to use density-adjusted reference amounts for aerated products in discrete units that vary widely in size and shape. The manufacturer adjusts for the difference in density of the aerated food relative to the regular product. For example, if the density of the aerated food is 30 percent lower than the density of the regular product, the density-adjusted reference amount for the aerated food would be 30 percent less than the reference amount of the regular counterpart.

FDA tentatively finds that a density-adjusted reference amount would not be appropriate for salt products for three reasons. First, unlike waffles, which are sold and consumed in discrete units, salt products are bulk products that are measured by volume. An aerated reference amount (i.e., density adjusted) is not appropriate, because there are no discrete units such that the regular and the aerated versions are ''the same in size, shape, and volume'' (see § 101.12(e)(1)).

Second, applying the rounding specifications for aerated reference amounts leads to an absurdity for products with small reference amounts like salt. Section 101.12(e) of FDA's regulations specifies that the reference amount for an aerated food ''shall be rounded to the nearest 5-g increment.'' The current reference amount for salt is 1 g. Thus, if a density-adjusted reference amount were calculated for a low-density salt product, it would be 0.67 g. Rounding 0.67 g to the nearest 5-g increment gives 0 g which is an illogical and nonsensical result.

Finally, § 101.12(e) requires that the product bear a descriptive term indicating that air has been incorporated (e.g., whipped, aerated). Describing the product as ''whipped salt'' or ''aerated salt'' is apt to be confusing to consumers given that the appearance and the consistency of the two salts are very similar. For these reasons, the concept of a density-adjusted reference amount for salt products is not appropriate.

C. Consideration of a Volumetric Reference Amount

The petition and supplemental submission support a volumetric reference amount for salt and salt products. As noted in the petition, in the proposed and final serving sizes regulations (56 FR 60394 and 58 FR 2229), FDA discussed its approach to products like salt that can easily be measured volumetrically. As discussed above, the agency considers volumetric reference amounts appropriate when three criteria are met: (1) The product can easily be measured volumetrically, (2) the densities vary widely, and (3) the amount customarily consumed is more uniform when expressed as a volume rather than a weight.

First, in order for a volumetric reference amount to be appropriate, the product must be a bulk product that can be measured volumetrically, such as peanut butter or fluids (final rule for serving sizes, comment 20, 58 FR 2229 at 2238 and comment 108, at 2263). Salt

and salt products can be measured volumetrically.

Second, there must be a significant difference in the densities (i.e., 25 percent or more) of the different forms of the product such that a range of densities are represented within the product category (see discussions on aerated products in § 101.12(e) and peanut butter (58 FR 2229 at 2263)). FDA considers the 33-percent density difference reported for low-density salt relative to conventional table salt to be significant and to justify a finding that the densities of different products within the category vary widely.

Third, the amount customarily consumed must be more uniform when expressed volumetrically than when expressed gravimetrically (56 FR 60394 at 60406 and 58 FR 2229 at 2238). There must be some indication or likelihood that similar volumes, rather than similar weights, of both low- and high-density products within the same product category are customarily consumed. The evidence must show that the amount that people consume is more consistent when expressed in volumetric terms than when expressed in terms of weight.

In the final serving sizes regulation (58 FR 2229 at 2260), FDA rejected a request for a volume-based reference amount for salt products, even though salt products are measured volumetrically. The agency observed that ''[t]he comment did not submit any data to support that regular salt and the low-density salt are consumed equally on a volume basis.'' FDA noted that like sugar, salt is used as a flavoring agent to attain a given level of saltiness. Thus, the agency stated, the reference amount for a salt substitute, such as a low-density salt product, should be the amount necessary to provide a salty taste equivalent to one reference amount of salt.

In reconsidering whether the amounts consumed of the various products within the salt category are more similar when expressed in terms of volume than in terms of weight, FDA looked at the quality of the supporting evidence submitted, including the study design, the results, and the conclusions. The agency evaluated the data provided in the supplementary submission and determined: (1) That the consumer research conducted on behalf of the petitioner is a reasonably well controlled experiment that meets scientific standards for testing household salt consumption differences due to two types of salt; and (2) that the result supports, but does not prove, the hypothesis that salt is used on a volumetric rather than on a weight basis (Ref. 2). Thus, FDA has tentatively concluded that the data provide evidence that similar volumes, rather than similar weights, of low- and high-density products are customarily consumed.

Section 101.12(e), which applies to discrete products like waffles, requires that the aerated version bear a descriptive term indicating that air has been incorporated (e.g., whipped, aerated). Some product categories that have volumetric reference amounts contain products whose common or usual names clearly indicate that air has been incorporated into the product (e.g., whipped peanut butter, whipped dessert topping). Some products in other product categories with volumetric reference amounts do not bear such descriptive terms (e.g., pudding, ice cream). Given these differences, FDA is requesting comments on whether low-density salt products should be required to clearly identify that they contain more air than conventional salt products. It is the agency's opinion that terms such as ''whipped salt'' or ''aerated salt'' are apt to be confusing to consumers. Therefore, FDA is also requesting comments on what kind of descriptive terms would be clear and nonmisleading for consumers.

IV. Conclusion

FDA has determined that volumetric reference amounts are appropriate when: (1) Products are bulk products that can be measured volumetrically; (2) there are significant differences in densities among the products within a product category such that a range of densities are represented within the particular product category; and (3) the amount customarily consumed is more uniform when expressed volumetrically, that is, there is some indication or likelihood that similar volumes, rather than similar weights, of both low- and high-density products within the same product category are customarily consumed.

The petition and supplemental submission contain information that evidences that similar volumes rather than similar weights of low- and high-density salt products are customarily consumed. Because the products within the category can be measured volumetrically, and the density difference among products within the same product category appear to be significant, FDA has concluded that the petitioner has made a prima facie showing that it is appropriate for the reference amount for salt and salt products to be expressed on a volumetric rather than a gravimetric (i.e., weight) basis.

FDA is proposing to change the reference amount for salt andsalt products from 1 g to 1/4 tsp and to solicit public comment on the proposed change. The agency selected 1/4 tsp because it is the volumetric amount that most closely reflects the amount customarily consumed. It is the smallest volumetric amount permitted in the regulations (21 CFR 101.9(b)(5)(i)). In addition, the 1/4 tsp reference amount will permit comparison with herbs and spices which also have a reference amount of 1/4 tsp.

V. Comments

Interested persons may, on or before October 4, 1995, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

VI. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because there is no cost to industry, the agency certifies that the proposed rule will not have a significant

economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VIII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

(1) Letter from Dykstra, Gary, to Wayne H. Matelski, dated July 11, 1995.

(2) Brenda Derby, Consumer Studies Branch, Division of Market Studies, memo to file, June 20, 1994.

(3) U.S. Department of Agriculture and Department of Health and Human Services (DHHS), ''Nutrition and Your Health: Dietary Guidelines for Americans,'' 3d ed., U.S. Government Printing Office, Washington, DC, 1990.

(4) DHHS, ''The Surgeon General's Report on Nutrition and Health,'' U.S. Government Printing Office, Washington, DC, 1988.

(5) National Research Council, ''Diet and Health. Implications for Reducing Chronic Disease Risk,'' National Academy Press, Washington, DC, 1989.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.12 is amended in paragraph (b), Table 2, under the ''Miscellaneous category'' by revising the entry for ''Salt, salt substitutes, seasoning salts (e.g., garlic salt)'' under the headings ''Reference amount'' and ''Label statement'' to read as follows:

§ 101.12 Reference amounts customarily consumed per eating occasion.

* * * * *

(b) * * *

TABLE 2.—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY[1, 2, 3, 4]

Product category	Reference amount	Label statement[5]
* * *	* *	* *
Miscellaneous category:		
* * *	* *	* *
Salt, salt substitutes, seasoning salts (e.g., garlic salt).	1/4 tsp	1/4 tsp (———g); ——— piece(s) (———g) for discrete pieces (e.g., individually packaged products)
* * *	* *	* *

[1] These values represent the amount (edible portion) of food customarily consumed per eating occasion and were primarily derived from the 1977–1978 and the 1987–1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.

[2] Unless otherwise noted in the Reference Amount column, the reference amounts are for the ready-to-serve or almost ready-to-serve form of the product (i.e., heat and serve, brown and serve). If not listed separately, the reference amount for the unprepared form (e.g., dry mixes; concentrates; dough; batter; dry, fresh, and frozen pasta) is the amount required to make the reference amount of the prepared form. Prepared means prepared for consumption (e.g., cooked).

[3] Manufacturers are required to convert the reference amount to the label serving size in a household measure most appropriate to their specific product using the procedures in 21 CFR 101.9(b).

[4] Copies of the list of products for each product category are available from the Office of Food Labeling (HFS–150), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

[5] The label statements are meant to provide guidance to manufacturers on the presentation of serving size information on the label, but they are not required. The term ''piece'' is used as a generic description of a discrete unit. Manufacturers should use the description of a unit that is most appropriate for the specific product (e.g., sandwich for sandwiches, cookie for cookies, and bar for ice cream bars). The guidance provided is for the label statement of products in ready-to-serve or almost ready-to-serve form. The guidance does not apply to the products which require further preparation for consumption (e.g., dry mixes, concentrates) unless specifically stated in the product category, reference amount, or label statement column that it is for these forms of the product. For products that require further preparation, manufacturers must determine the label statement following the rules in § 101.9(b) using the reference amount determined according to § 101.12(c).

* * * * *

Dated: June 26, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–17919 Filed 7–20–95; 8:45 am]

BILLING CODE 4160–01–F